

**REMARKS**

Claims 1-8, 11 and 13-23 are currently pending. Claims 1, 11 and 13-16 are amended to advance prosecution and without prejudice to the prosecution of subject matter cancelled by amendment in other patent applications. The amended claims are supported by the original claims and the specification, particularly at page 6, lines 17-29; and page 19, line 25, continuing to page 20, line 5. Claims 9, 10 and 12 are canceled. Claims 24-30 are canceled as a result of the restriction requirement and without prejudice to the prosecution of their subject matter in other patent applications. No new matter is added by way of these amendments.

The Examiner has rejected claims 1-23 under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps. The Examiner has rejected claims 1-3 under 35 U.S.C. § 102(b) as being anticipated by Gan et al. (U.S. Patent 5,523,316 by Gan et al.) (“Gan et al.”). The Examiner has rejected claims 4-8 and 18-23 under 35 U.S.C. § 103(a) as being obvious over Gan et al. in view of Calvin et al. (Calvin et al., 1997, Progression of mouse buthionine sulfoximine cataracts in vitro is inhibited by thiols or ascorbate Exp. Eye Res., 65:341-347) (“Calvin et al.”). The Examiner has also rejected claims 9-17 under 35 U.S.C. § 103(a) as being obvious over Gan et al. in view of Komiya (Komiya, 1997, Synthesis of organometallic compounds: A practical guide. John Wiley and Sons, UK, pg. 35-50) (“Komiya”). For the reasons detailed below, the rejections should be withdrawn and the claims should be allowed to issue.

**I. Rejection under 35 U.S.C. § 112, second paragraph**

Claims 1-23 stand rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps

The Examiner contends that the claims omit the essential steps of measurement of oxygen concentration levels before vitrectomy, directly after vitrectomy, and during the surgical procedure. The Examiner alleges that further method steps involve the use of a vitrectomy cutting instrument for cutting and removing a part of the vitreous, followed by degassing of the replacement solution, and introduction of a degassed aqueous solution having glutathione and/or ascorbic acid into the eye.

Applicant asserts that the presently amended claims address the basis for the Examiner's rejection. Applicant notes that the invention encompasses a method of protecting against cataract development by replacing vitreous humor with a low oxygen-concentration vitreous replacement solution, not the measurement of oxygen concentration levels in the eye of a subject before, during, and after a vitrectomy. Applicant has shown that oxygen levels in an eye following vitrectomy in which the vitreous is replaced with BSS (Balanced Salt Solution), an air-saturated vitreous replacement solution (page 19, lines 10-13), are higher than oxygen concentrations in un-operated eyes (page 48, lines 1-14). Applicant also asserts that high levels of oxygen in the vitreous and lens leads to cataract development (page 19, lines 10-14), likely through the generation of activated oxygen species (page 4, lines 11-25). The invention as presently claimed is directed to reducing the oxygen in the vitreous following vitrectomy by using a low oxygen-concentration vitreous replacement solution rather than an air-saturated solution as currently used by those skilled in the art. To practice the claimed invention it is not necessary to measure the oxygen levels in the eye before, during or after a vitrectomy. It is necessary to replace the vitreous humor with a low oxygen-concentration vitreous replacement

solution. The process of performing a vitrectomy, for example, using a cutting instrument to remove the vitreous and replace it with a vitreous replacement solution, is known in the art. Applicant asserts that the novelty of the invention resides in the use of a low oxygen-concentration vitreous replacement solution, and not the surgical procedure. A skilled artisan would have the knowledge to make and use the invention as presently claimed, *i.e.* replace the vitreous humor with a low oxygen-concentration vitreous replacement solution. Applicant therefore asserts that the claims do not omit essential steps, and request that the rejection be withdrawn.

## **II. Rejections under 35 U.S.C. § 102(b)**

### **A. Gan et al. does not anticipate the claims**

Claims 1-3 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Gan et al. According to the Examiner, Gan et al. describes an ophthalmic irrigating solution comprising antioxidants, such as glutathione and ascorbic acid.

Applicant asserts that the presently amended claims are not anticipated by Gan et al. Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. See M.P.E.P. § 2131 (8th Ed. Rev. 3, August 2005). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Every element of the claimed invention must literally be present, arranged as in the claim. *Perkin Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 U.S.P.Q. 669, 673 (Fed. Cir. 1984).

Applicant submits that the solution of Gan et al. and the vitreous replacement solution of the presently amended claims are different. The currently amended claims encompass a low oxygen-concentration vitreous replacement solution in which a portion of oxygen has been removed from the solution by introducing an essentially-oxygen-free gas into the solution, and/or subjecting the solution to a partial vacuum. Gan et al., describes a vitreous replacement solution comprising two parts which are mixed together prior to use in a vitrectomy. The formulations of the two parts is similar to that of BSS Plus (column 8, lines 23-29; and column 10, lines 38-46) supplemented with antioxidants such as glutathione and ascorbic acid, which scavenge oxygen free radicals produced in the eye through photochemical oxygen activation (column 7, lines 50-65). Gan et al. does not remove oxygen from a vitreous replacement solution by introducing an oxygen-free gas into the solution, or by subjecting the solution to a vacuum. Applicant asserts that BSS and BSS Plus irrigation solutions are air-saturated solutions that would therefore contain high levels of oxygen (page 19 lines 7-13 of the specification). Thus, the claimed invention is different than the solution described by Gan et al.

### **III. Rejections under 35 U.S.C. §103(a)**

#### **A. The claims are novel over Gan et al. in view of Calvin et al.**

Claim 4-8 and 18-23 stand rejected under 35 U.S.C. § 103(a) as being obvious over Gan et al. in view of Calvin et al. The Examiner contends that Calvin et al. describes the induction of cataracts in a lens by decreasing lens glutathione levels through treatments with buthionine sulfoximine, a glutathione synthesis inhibitor. Furthermore, the induction of cataracts can be prevented by supplementing the treatments with 1 mM ascorbate or 2 mM glutathione. The Examiner contends that combining the vitreous replacement solution of Gan et al. with the

concentrations of ascorbate and glutathione described in Calvin et al. obviates the claimed invention.

A *prima facie* case of obviousness must establish that (1) there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there is a reasonable expectation of success; and (3) the prior art reference (or references when combined) teach or suggest all the claim limitations. See M.P.E.P. §§ 706.02(j) and 2143. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, rather than Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q2d 1438 (Fed. Cir. 1991).

Applicant submits that the combination of the teachings of Gan et al. with that of Calvin et al. does not render the presently claimed invention obvious because the combination does not teach or suggest all the limitations of the presently amended claims. As described previously, the presently claimed invention encompasses a low oxygen-concentration vitreous replacement solution in which a portion of oxygen has been removed from the solution by introducing an essentially-oxygen-free gas into the solution, and/or subjecting the solution to a partial vacuum. The vitreous replacement solution of Gan et al. comprises formulations similar to BSS Plus, an air-saturated replacement solution supplemented with antioxidants. Gan et al. does not remove oxygen from the solution by introducing an oxygen-free gas into the solution, and/or subjecting the solution to a vacuum. The claimed vitreous replacement solution and that of Gan et al. are therefore different. Consequently, combining the solution of Gan et al. with the ascorbate and glutathione of Calvin et al. does not obviate the claimed invention because it does not describe all of the limitations of the presently amended claims. As such, Applicant requests that the rejection be withdrawn.

**B. The claims are novel over Gan et al. in view of Komiya**

Claim 9-17 stand rejected under 35 U.S.C. § 103(a) as being obvious over Gan et al. in view of Komiya. The Examiner contends that Komiya describes methods for removing oxygen from a solution by bubbling Ar or N<sub>2</sub> through the solution, or through the use of vacuum lines to remove traces of air. Komiya further teaches the use of specialized glassware to work in an inert atmosphere. The Examiner contends that the combined teachings of Gan et al. and Komiya describes the removal of air from a low oxygen-concentration vitreous replacement solution, rendering the claims obvious.

Applicant asserts that the presently amended claims are not obvious over Gan et al. in view of Komiya. Applicant asserts that there would be no motivation to combine the teachings of Gan et al. with that of Komiya. Gan et al. describes a vitreous replacement solution designed to control intraocular pressure following vitrectomy. Gan et al. supplements an air-saturated vitreous replacement solution with agents to reduce intraocular pressure, as well as antioxidants to reduce oxidative damage to corneal endothelial cells from the photochemical activation of oxygen. Gan et al. states that long exposure to light during intraocular surgical procedures results in an incessant generation of activated oxygen in the eye (column 7, lines 50-65). Supplementing the vitreous replacement solution with antioxidants combats this increase in oxygen radicals. Thus, Gan et al. is directed towards a vitreous replacement solution with increased radical scavenging properties.

Komiya, in contrast, has no relationship to vitreous replacement solutions, cataracts, or ophthalmology, but rather relates to organic synthesis and techniques for achieving an inert atmosphere. Applicant respectfully suggests that the Examiner has combined Komiya

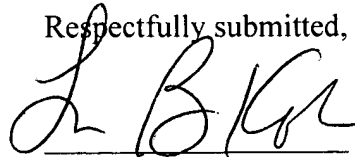
and Gan, et al. in an attempt to piece together the invention with the benefit of hindsight, which is improper. Accordingly, the rejection of the claims should be withdrawn.

#### IV. CONCLUSION

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. Applicant believes that the invention described and defined by amended claims 1-8, 11 and 13-23 are in condition for allowance. Withdrawal of all rejections and reconsideration of the amended claims is requested. An early allowance is earnestly sought.

Applicant believes that no additional fees are due in the filing of this response. In the event that fees are due, or overpayment is made, however, the Director is hereby authorized to charge payment of any such fees, or to credit any overpayment, to Deposit Account No. 02-4377.

Respectfully submitted,



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Enclosures